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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,767	07/28/2003	David A. Ferrera	MICRU-65125	5783

24201 7590 08/23/2006

FULWIDER PATTON
6060 CENTER DRIVE
10TH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
SONNETT, KATHLEEN C	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,767	FERRERA ET AL.	
	Examiner	Art Unit	
	Kathleen Sonnett	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *148-177* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *148-177* is/are rejected.

7)☒ Claim(s) *164* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/28/03,9/8/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: in the amendment to the specification filed on 7/28/2003, it is mentioned that the instant application is a continuation of application 09/762,539. Application 09/762,539 is now U.S. Patent No. 6,616,617. It is suggested that this information be added to the specification.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. **Claims 165-173 and 174-177** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 11-14 of U.S. Patent No. 6,616,617. Although the conflicting claims are not identical, they are not patentably distinct from each other. The independent claim 1 of U.S. Patent No. 6,616,617 claims the enlarged portions being disposed within the shape memory coil and independent claim 165 of the instant

application claims the enlarged portions being disposed within the outer coil portion of the shape memory portion. It would be obvious to one of ordinary skill in the art to include the enlarged portions (which are radiopaque) in the outer coil portion since this would allow more of the device to be visible.

3. **Claims (154, 155) and 161** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim (13) and claim 19, respectively, of U.S. Patent No. 6,159,165. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 154 and 155 of the instant application are merely broader than claim 13 of U.S. Patent No. 6,159,165.

4. Regarding claim 161, although claim 19 of U.S. Patent No. 6,159,165 does not claim collagen or a modified polymer with growth factors as the therapeutic agent. However, collagen forms the base of many hydrogels and growth factors are well known therapeutic agents. Therefore, it would be obvious to one of ordinary skill in the art to modify the claimed invention of claim 19 of U.S. Patent No. 6,159,165 to include a hydrogel made of collage or a growth factor as the therapeutic agent since these are commonly used tissue growth enhancers in the medical arts.

5. **Claims 156 and 157** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 6,159,165 in view of Mirigian et al. (U.S. 5,549,624). Claim 13 claims the invention of claims 156 and 157 of the instant application except for the at least one therapeutic fiber being woven about adjacent or non-adjacent loops of the coil. However, Mirigian et al. discloses that it is old and well known in the art to use both of these conventions (see Fig. 2 and Fig. 3) in order to hold a therapeutic fiber in place so that they are not released from the coil. Therefore, it would have been obvious to one of ordinary skill in the art to modify the claimed invention of claim 13 of U.S. Patent No.

6,159,165 to include weaving the therapeutic fiber about non-adjacent or adjacent loops of the coil as made obvious by Mirigian et al. in order go gain the advantage having the fibers tightly connected to the coil.

6. **Claims 154-157** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,171,326 in view of Mirigian et al. (U.S. 5,549,624). Claims 154-157 of the instant application are merely broader than claim 5 of U.S. Patent No. 6,171,326 except for the addition of at least one therapeutic fiber woven into the coil to enhance treatment of the site after placement of the device. However, Mirigian et al. discloses that it is old and well known in the art to include therapeutic fibers that increase thrombogenicity resulting from an occlusive device (col. 2, lines 38-42). Additionally, Mirigian et al. discloses weaving the therapeutic fiber about non-adjacent or adjacent loops of the coil (see Fig. 2 and 3). Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention claimed in claim 5 of U.S. Patent No. 6,171,326 to include at least one therapeutic fiber woven into the coil to enhance treatment of the site after placement of the device, woven either about adjacent or non-adjacent loops of the coil as made obvious by Mirigian et al. in order to enhance thrombogenicity.

Claim Objections

7. Claim 164 is objected to because of the following informalities: typographical error. Line 1 of the claim should read "at least one flexible". Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **Claims 150, 153, 158 and 159** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 150 and 153 recite the limitation "said central three dimensional coil" in line 2. There is insufficient antecedent basis for this limitation in the claims.

11. Claims 158 and 159 recite the limitation "the multiple strands" in line 2 of each claim. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

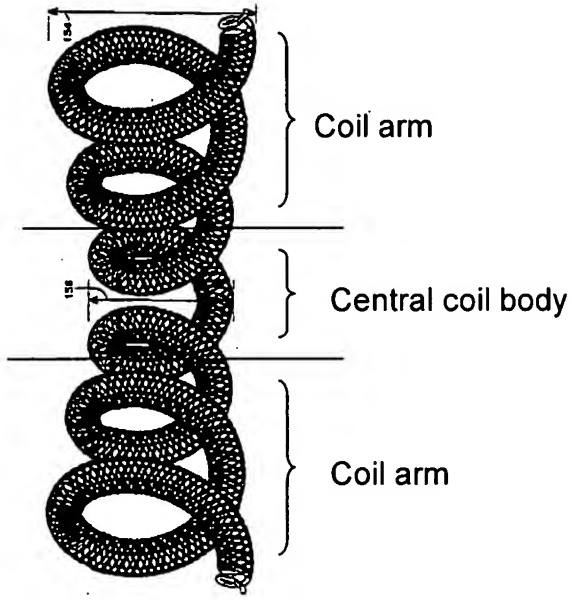
13. **Claims 148-150, and 152-153** are rejected under 35 U.S.C. 102(b) as being anticipated by Phelps et al. (U.S. 5,382,259). Phelps et al. discloses an occlusive device for use in interventional therapy and vascular surgery, adapted to be inserted into a portion of a vasculature, the occlusive device comprising a plurality of coil arms formed of shape memory material having a collapsed primary coil configuration and a three dimensional, polyhedral expanded secondary configuration, the coil arms having inner and outer ends and the inner

ends of the coil arms being connected together and a central coil body connected to the inner ends of the coil arms (col. 3 lines 26-31; Fig. 16).

14. Regarding claim 149, the coil arms are formed from conically shaped coils connected to the central body and having an expanding diameter as they radiate outward (see Fig. 16).

15. Regarding claim 150, the central three dimensional coil has a rounded shape.

16. Regarding claims 152 and 153, the coil arms and central coil each comprise a secondary wind coil of a primary helical wind coil.



17. **Claims 154, and 156-157** are rejected under 35 U.S.C. 102(b) as being anticipated by Mirigian et al. (U.S. 5,549,624).). Mirigian et al. discloses a device for use in interventional therapy and vascular surgery, adapted to be inserted into a portion of a vasculature comprising a coil (102) having a collapsed primary coil configuration and an expended secondary configuration with a three dimensional shape (Fig. 6), the coil being formed from at least one flexible strand of a resilient material (col. 2 line s 26-29) and at least one therapeutic fiber (104) woven into the coil to enhance treatment of the site after placement of the device (see abstract).

18. Regarding claim 156, see Fig. 3 (at least one fiber, i.e. (110, 112, and 114), are woven about adjacent loops of the coil).

19. Regarding claim 157, see Fig. 2.

20. **Claims 154, 156-157, and 163** are rejected under 35 U.S.C. 102(e) as being anticipated by Mirigian et al. (U.S. 5,700,258). Mirigian et al. discloses a device for use in interventional therapy and vascular surgery, adapted to be inserted into a portion of a vasculature comprising a coil (102) having a collapsed primary coil configuration and an expended secondary configuration with a three dimensional shape (col. 2 lines 25-33), the coil being formed from at least one flexible strand of a resilient material (col. 2 line 56) and at least one therapeutic fiber woven into the coil to enhance treatment of the site after placement of the device (see lines 3-5 of abstract).

21. Regarding claim 156, see Fig. 10

22. Regarding claim 157, see Fig. 1.

23. Regarding claim 163, see Fig. 12.

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. **Claim 151** is rejected under 35 U.S.C. 103(a) as being unpatentable over Phelps et al. in view of Engelson et al. (U.S. 5,423,849). Phelps discloses the invention as stated above including a plurality of coil arms and a multistranded micro-cable (162) having a plurality of

flexible strands of a resilient material but fails to disclose at least one radiopaque strand included in the cable.

26. However, Engelson et al. discloses that it is old and well known in the art to include radiopaque fibers in braided cables of occlusive devices (see claim 1 and col. 3 lines 26-30) to increase visibility of the device. As disclosed by Engelson et al., the fibrous elements such as those disclosed by Phelps are important for tissue growth but are not normally radiopaque and make retrieval of the device difficult. Engelson et al. discloses that this braid is desirable in that the ratio of fibrous to metallic material is quite high which increases embolic and tissue growth (col. 1 lines 50-60) but it has enhanced radipacity due to the metallic strands in the braid (col. 2, lines 30-33).

27. **Claims 155, 159, and 164** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mirigian et al. in view of Engelson et al. (U.S. 5,423,849). Mirigian et al. discloses the invention substantially as stated above including the at least one flexible strand providing a radiopaque marker, but fails to disclose that the at least one flexible strand comprises a plurality of flexible strands of a resilient material.

28. However, Engelson et al. discloses that it is old and well known in the art to have a flexible strand that comprises a plurality of flexible strands of a resilient material and at least one radiopaque strand to provide a radiopaque marker of the deployed configuration of the device in an occlusion device that includes therapeutic fibers. Engelson et al. discloses that the occlusive braid is desirable in that the ratio of fibrous material to metallic material is high, which encourages embolic and tissue growth (col. 1 lines 50-54). Also, the therapeutic fibers (144) are held firmly in place due to the braided configuration (col. 1 lines 55-60). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of

Mirigian et al. to include a plurality of flexible strands as made obvious by Engelson et al. in order to encourage embolic and tissue growth.

29. Regarding claim 159, the modified device of Mirigian et al. includes at least one flexible strand that comprises a plurality of braided flexible strands and at least one radiopaque strand. Mirigian et al. discloses weaving the fibers into adjacent loops of the coil and Engelson et al. as mentioned above, makes obvious weaving the fiber through multiple strands as seen in Fig. 4 of Engelson et al. in order to hold the fibers firmly in place (col. 1 lines 55-60).

30. Regarding claim 164, Mirigian et al. discloses the invention substantially as stated above, but fails to disclose that the strand comprises a nickel-titanium alloy. However, Engelson et al. discloses that it is old and well known in the art to use a nickel-titanium alloy (Nitinol) because Nitinol wire has the proper transition temperature to allow the device to be introduced through a catheter in a linear fashion and upon raising the temperature of the occlusive braid to body temperature, the wire assumes its pre-selected shape (col. 3 lines 13-19). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Mirigian et al. to include a strand comprising a nickel-titanium alloy as made obvious by Engelson et al. in order to gain the advantage of being able to introduce the device through a catheter in a linear fashion.

31. **Claims 160-162** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mirigian et al. in view of Snyder (U.S. 5,658,308) and Lau et al. (U.S. 5,876,432). Mirigian et al. discloses the invention substantially as stated above, but fails to disclose that the therapeutic fiber is made of a material that will provide a timed release of a therapeutic agent intended to become active after placement of the device.

32. However, Snyder discloses that it is old and well known in the art to make occlusion coils bioactive. In particular, Snyder discloses the use of therapeutic fibers made of modified

polymers that carry drugs or growth factors through chemical bonding. Lau et al. discloses that chemical bonding of therapeutic agents to medical devices is well known in the art and can incite local cells to produce new collagen or tissue (col. 17, lines 62-64). Furthermore, by varying the chemical linkage between the device material and the growth factor, it is possible to provide a timed release, which allows a desired rate of release to be achieved (col. 18, lines 15-35). Lau et al. discloses several different growth factors that can be used to facilitate regrowth. Lau et al. does not disclose incorporating different agents on different fibers. However, applicant has not disclosed that providing the different agents on different fibers provides any advantage or solves any problem over incorporating several different agents on each individual fiber. One of ordinary skill in the art, furthermore, would expect either convention to work equally well. It would be an obvious matter of design choice to one of ordinary skill in the art to include different therapeutic agents on different fibers to provide different therapies. Therefore, it would have been obvious to one or ordinary skill in the art to modify the device of Mirigian et al. to include a therapeutic agent such as a growth hormone that is time released as made obvious by Snyder and Lau et al. in order to gain the advantage of being able to have a long term treatment that induces tissue growth.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. 6,399,886 to Avellanet.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS
8/8/2006

GLENN K. DAWSON
PRIMARY EXAMINER